



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,277	08/02/2002	David Andrewes	WPT0006	6080
25235	7590	06/22/2006		
HOGAN & HARTSON LLP ONE TABOR CENTER, SUITE 1500 1200 SEVENTEENTH ST DENVER, CO 80202			EXAMINER LEVKOVICH, NATALIA A	
			ART UNIT 1743	PAPER NUMBER

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,277	ANDREWES ET AL.	
	Examiner	Art Unit	
	Natalia Levkovich	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19 and 36-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19 and 36-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the collection chambers, the filter, the 'means for breaking the surface tension' and the frit must be clearly shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

Art Unit: 1743

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 19-~~44~~55 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, line 9, the "web or like member" is indefinite because the claim includes elements not actually disclosed (those encompassed by "or like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). It is also not clear how the filter is related to the 'means for breaking', since a filter can be considered a 'surface tension breaker'.

Claim 38 recites that 'the paddle includes ...means for supporting the paddle'. The structural inter-relationships between the means and the paddle are unclear.

Claim Interpretation

4. Referring to claims 47-55, since the instrument is not positively claimed, it is not considered to be a part of the claimed invention. Therefore, the instrument and its parts

Art Unit: 1743

(such as switches) are not accorded patentable weight. Note that it has been held that the recitation that an element is 'adapted to' perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense (see *In re Hutchison*, 69 USPQ 138).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 19, 36-38 and 45-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd et al. (US 5122284) in view of Buechler (US 6156270), and further in view of Hammer (US 6531095).

Burd discloses an apparatus for blood separation with and subsequent optical analysis. The apparatus "comprises a plurality of internal chambers and passages for combining the plasma with one or more reagents and distributing the plasma to a plurality of

Art Unit: 1743

individual test wells”(Abstract). As shown in Figure 1, the structure x 12 includes a blood application port 22 [‘funnel shaped inlet port’ – Ex.] and chamber 40 and 44 each having an inlet.

Burd does not teach an inlet port having a filter and a ‘web or like member. Buechler discloses assay devices which include flow control and measurement elements. The flow control structures, such as reservoirs, capillaries, may include filter membranes, meshes, etcetera, in order to “filter particulates from the sample or ... blood cells from blood so that plasma can further travel through the device”(Col.8, lines 50-55; Claim 19). It would have been within an ordinary skill of the art at the time the invention was made to have employed a porous element (such as a mesh, web, frit or membrane filter) in the outlet section of the inlet port of the modified apparatus of Burd, in order to filter out particulates or foreign matters from a sample.

Although Burd does teach mixing (for example, in column 9, line 20 the patent teaches that “the geometry of collection chamber 90 may be modified to promote mixing of the separated biological fluid, e.g., plasma, with a diluent or reagent ...”), the reference does not specify the type of mixing elements, in particular, magnetic or piezoelectric ones. However, such elements are commonly used in the art. Hammer, for example, discloses an “analytical instrument for analyzing fluids”(Abstract). The instrument includes a cartridge carousel assembly with analytical cartridges, an optical detector and a magnetic mechanism 161 (Figure 17). “The magnet 161 is used in combination with magnetic particles ‘paddlesadapted for undergoing a reciprocating motion’ – Ex.] which may be included in the cartridges to provide mixing of reagents and samples

Art Unit: 1743

within the cartridges as they pass by the magnet”(Col.9, line 45). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed magnetic (or piezoelectric) mixing elements in the modified apparatus of Burd, in order to provide mixing of fluids in any chamber without overcomplicating the structure with electrically driven mixing elements.

Allowable Subject Matter

8. Claims 39-44 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The prior art does not teach, or fairly suggest an apparatus where a fluidic structure specified in claim 19 would have a T-shaped magnetic or piezoelectric mixing element, as recited in claims 39-44.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

Art Unit: 1743

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 19 and 36-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-3 of U.S. Patent No. 6300142.


Although the conflicting claims are not identical, they are not patentably distinct from each other because all the elements (except the 'web or like member' in the inlet port and the mixing element ('paddle')) of the invention recited in claims 19 and 36-46 of the instant application, are recited in the claims 1-3 of U.S. Patent No. 6300142. With respect to the paddle and the 'web or like member', it would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed a mixing element and an additional filtering means ['web or like'], in the modified apparatus of U.S. Patent No. 6300142, in order to provide better mixing and filtration of the fluids.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jill Warden
Supervisory Patent Examiner
Technology Center 1700